

## **REMARKS**

### **I. Introduction**

Applicants respectfully request reconsideration of the present application in view of the reasons given below. In addition, Applicants gratefully acknowledge the courtesy extended by Mr. Joseph McKane to their representative during a telephone discussion on February 16, 2004 concerning the present restriction requirement. The following commentary incorporates the substance of that discussion.

### **II. Status of the Claims and Amendments to the Application**

Claims 42 and 43 are cancelled as a consequence of the amendment to claim 37. Claims 37-41 and 44-53 are therefore pending.

Applicants' reply to the PTO's requirement to restrict resulted in the PTO withdrawing claims 47-53 as well as subject matter within the elected group. After entry of the foregoing amendments, claims 37-41 and 44-46 are being examined on the merits.

In response to the PTO's helpful suggestions, Applicants amended the specification at pages 88 and 89. Specifically, that portion of Table 1 appearing on page 88 has now been identified as "Table 1, cont." Additionally, a concluding paragraph on page 89 has been amended to remove certain objectionable language.

### **III. The Office Action**

Applicants thank the PTO for acknowledging the allowability of the "elected invention" pending a satisfactory resolution of the double-patenting issues that are discussed below. Office Action at page 5. Applicants first turn to the merits of the restriction requirement.

#### **A. Restriction Requirement**

The PTO maintained the propriety of its requirement to restrict examination to elected Group I (claims 37-46). In light of Applicants' compliance with the additional requirement to

elect a species, the PTO further restricted examination to that subgenus of the elected group wherein R<sup>3</sup> and R<sup>4</sup> combine to form an unsubstituted pyrrolidin-1-yl moiety, all other variables being defined as set forth in claim 37. The stated rationale for withdrawing all other subject matter from Applicants' elected invention hinges upon two points. First, the PTO posited authority under 35 U.S.C. § 121 to restrict examination to one of several independent and distinct inventions encompassed by a Markush-style claim. Second, as Examiner McKane patiently explained, the elected claims read on compounds that are variously classified, which supports the first point, and therefore foists undue search and examination burdens upon the PTO. Because the Director not only countenances but requires that Markush-style claims be examined in their entirety under circumstances like the present, Applicants must respectfully traverse the requirement to restrict.

Following an Applicant's election of a species, the PTO is obligated to fully search and examine a Markush-type generic claim "with respect to the elected species *and further to the extent necessary* to determine patentability." MPEP § 803.02 (August 2001) (emphasis added). This is especially true when the claim includes independent and distinct inventions. *Id.* Only when the PTO finds that the elected species and claims readable thereon are anticipated or obvious can non-elected subject matter be withdrawn. But where, as here, the PTO should find no prior art that anticipates or renders obvious the elected species, *see* Office Action at page 5, the search of the claim will be extended. *See* MPEP § 803.02. This is exactly the procedure by which the Director, in his authority under 35 U.S.C. § 121, can limit examination as to Markush-type generic claims.

Applying these principles to the case at hand, the PTO should not have withdrawn from examination all subject matter in which R<sup>3</sup> and R<sup>4</sup> do not combine to form a unsubstituted pyrrolidin-1-yl moiety. Rather, the PTO should properly extend its examination of the claims to subject matter beyond this subset of compounds. This is so because the PTO explicitly stated that no art of record anticipates or renders obvious the elected species.

The procedure outlined above does not consider whether examination of a Markush-type generic claim is unduly burdensome to the PTO. Nonetheless, Applicants kindly advise

that extending examination as urged above would entail a consideration of only thirteen (13) additional and discrete moieties for R<sup>3'</sup> and R<sup>4'</sup>.

For the foregoing reasons, and on Examiner McKane's helpful suggestion, Applicants courteously invite the PTO to reevaluate complying with the Director's procedure for examining the invention in its entirety as elected by Applicants.

## B. Objections

Applicants believe that the amendments above should moot the objections concerning pages 88 and 89 of the specification. Office Action at pages 4-5.

The PTO additionally objected to the claims for containing non-elected subject matter. Office Action at page 5. Since the objection turns entirely upon the impropriety of the restriction requirement discussed above, Applicants kindly decline the PTO's invitation to cancel "non-elected"<sup>1</sup> subject matter until such time as a satisfactory indication is presented as to what subject matter will be examined.

## C. Double-Patenting

### a. Rejections Over Issued Patents

Claims 37-42 and 46 stand rejected over claims 1-9 of U.S. Pat. No. 6,451,838 ("'838 patent") under the doctrine of obviousness-type double patenting. Office Action at page 6. Claims 37-43 and 46 are similarly rejected over claims 1-9 of U.S. Pat. No. 6,710,067 ("'067 patent"). Office Action at page 8. Applicants respectfully traverse these rejections.

The present invention would not constitute an improper extension of the '838 or '067 patent because the present claims do not encompass obvious variants of the compounds that are claimed in the cited patents. Where, as here, the application at issue is the later filed application, or the cited patents and application, an obviousness-type double patenting

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<sup>1</sup> Applicants wish to remove any doubt for the record that their "elected invention" or the "elected subject matter" is precisely that which Applicants elected in their response dated September 24, 2004, and it is not the narrower subgenus of subject matter that the PTO repeatedly characterizes as the "elected invention." See, e.g., Office Action at page 3.

rejection is proper only where the invention defined in a claim of the application is an obvious variation of the invention defined in a claim in the patent. *See MPEP § 804(II)(B)(1).*

Here, the claimed subject matter is a narrow selection of the claimed genus in the '838 and '067 patents. Specifically, R<sup>9</sup> as presently claimed is “-C(=O)NHR<sup>13</sup> wherein R<sup>13</sup> is lower alkyl substituted with amino or heteroalicyclic and optionally substituted with hydroxyl.”

The corresponding substituent also designated as R<sup>9</sup> in the '838 and '067 patents includes many organic substituents. However, “-C(=O)NHR<sup>13” per se is not one of those claimed substituents. The selection here of a specific value for R<sup>9</sup> cannot therefore be viewed as an obvious variant of the genus of substituents claimed in the '838 and '067 patents. Consequently, the claims as amended engender no double-patenting issues. Accordingly, Applicants respectfully urge the PTO to reconsider and withdraw the rejections.</sup>

### b. Rejections Over Pending Applications

Claim 46 stands provisionally rejected over claims 16, 18, 19, 36, 38, and 39 of co-pending application No. 10/300,390 under the doctrine of obviousness-type double patenting. Office Action at page 10. Claims 37-41 and 43-46 similarly stand rejected over claims 22-25 and 27-30 of co-pending application No. 10/429,895. Office Action at page 11. Finally, claims 37-41 and 43-46 stand rejected over claims 60-62, 65, 66, “74-48”, and 97-99 of co-pending application No. 10/774,415. Office Action at page 12.

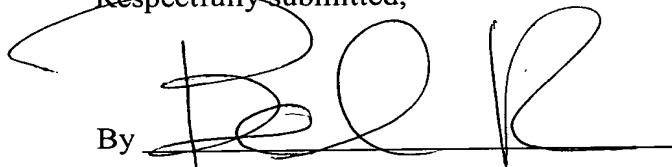
Applicants acknowledge the rejections, but respectfully defer a substantive response to each until such time as allowable subject matter has been indicated in one or more of the cited applications. Applicants therefore kindly request the PTO to hold the rejections in abeyance until that time, or withdraw them altogether if appropriate.

#### IV. Conclusion

Having satisfactorily addressed each of the outstanding issues, Applicants believe that the present application is now in condition for allowance subject to a fair treatment of the restriction requirement and related withdrawn subject matter. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is courteously invited to contact the undersigned by telephone if she feels that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

By



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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.